

Pediatric CIRB Meeting Agenda

January 13, 2022

I. Continuing Review

AALL1131, A Phase III Randomized Trial for Newly Diagnosed High Risk B-Lymphoblastic Leukemia (B-ALL) Including a Stratum Evaluating Dasatinib (IND#73789, NSC#732517) in Patients with Ph-like Tyrosine Kinase Inhibitor (TKI) Sensitive Mutations (Protocol Version Date 01/12/21)

II. Continuing Review

AAML1531, Risk-stratified Therapy for Acute Myeloid Leukemia in Down Syndrome: A COG Groupwide Phase III Study (Protocol Version Date 09/18/20)

III. Continuing Review

ANBL17P1, A Pilot Induction Regimen Incorporating Chimeric 14.18 Antibody (ch14.18, dinutuximab) (NSC# 764038, IND# 4308) and Sargramostim (GM-CSF) for the Treatment of Newly Diagnosed High-Risk Neuroblastoma (Protocol Version Date 10/24/19)

IV. Continuing Review

APAL2020SC, Pediatric Acute Leukemia (PedAL) Screening Trial – Developing New Therapies for Relapsed Leukemias (Protocol Version Date 10/28/21)

V. Continuing Review

ARST1431, A Randomized Phase 3 Study of Vincristine, Dactinomycin, Cyclophosphamide (VAC) Alternating with Vincristine and Irinotecan (VI) Versus VAC/VI Plus Temsirolimus (TORI, Torisel, NSC# 683864) in Patients with Intermediate Risk (IR) Rhabdomyosarcoma (RMS) (Protocol Version Date 11/16/20)

VI. Continuing Review

PBTC-049, A Phase I study of Savolitinib in Recurrent, Progressive or Refractory Medulloblastoma, High-Grade Glioma, Diffuse Intrinsic Pontine Glioma and CNS tumors harboring MET aberrations. (Protocol Version Date 05/12/21)

VII. Continuing Review

PBTC-058, Phase 2 Study of Intraventricular Omburtamab-based Radioimmunotherapy for Pediatric Patients with Recurrent Medulloblastoma and Ependymoma (Protocol Version Date 05/28/21)

VIII. Continuing Review

PED-CITN-03, Phase 1 Trial of Hu5F9-G4 (Magrolimab) Combined with Dinutuximab in Children and Young Adults with Relapsed and Refractory Neuroblastoma or Relapsed Osteosarcoma (Protocol Version Date 07/30/21)

IX. New Study - Initial Review

ACCL21C2, Prospective Cohort Study to Evaluate Immunologic Response Following COVID-19 Vaccination in Children, Adolescents and Young Adults with Cancer (Protocol Version Date 12/14/21)

X. New Study - Initial Review

AOST2031, A Phase 3 Randomized Controlled Trial Comparing Open vs Thoracoscopic Management of Pulmonary Metastases in Patients with Osteosarcoma (Protocol Version Date 12/20/21)

XI. New Study - Initial Review

ASCT2121, A Phase 2 Trial of Low-Dose Aldesleukin (Interleukin-2; IL-2) for Steroid-Refractory Chronic Graft-versus-Host Disease in Children (Protocol Version Date 09/10/21)

XII. Unanticipated Problem and Serious and/or Continuing Noncompliance Review

PBTC-055, Phase I/II trial of Dabrafenib, Trametinib, and Hydroxychloroquine (HCQ) for BRAF V600E-mutant or Trametinib and HCQ for BRAF fusion/duplication positive or NF1-associated recurrent or progressive gliomas in children and young adults (Protocol Version Date 05/05/21)
